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K955457

SIEMENS

510(k) SUMMARY

I. **GENERAL INFORMATION:**

Establishment:

•Address:	Siemens Medical Systems, Inc. 186 Wood Avenue South Iselin, NJ. 08830
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Date of Summary Preparation:	November 27, 1995

Device Name:

•Trade Name:	DIGISCAN 2 PLUS
•Common Name:	Digital Luminescence Radiography System
•Classification Name:	System, Image Processing: CFR: 90 LLZ.
•Classification:	Class II
Performance Standards:	21 CFR, Subchapter J

II. **SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.**

Performance Standards:

All components to which the above referenced performance standards apply are certified to conform with 21 CFR Subchapter J.

Device Description:

The DIGISCAN 2 PLUS is an X-ray recording medium used for routine radiographic examinations. Instead of utilizing conventional radiographic screens (e.g. silver halide), the DIGISCAN 2 PLUS system employs phosphor plate technology. The system may be used for all radiographic exposures in which conventional cassettes are used, such as GI, and vascular radiography.The processed radiographic images may be sent to a hardcopy device, or an archive.

The DIGISCAN 2 PLUS will be made commercially available in three models: the DIGISCAN 2H PLUS, DIGISCAN 2C PLUS and the DIGISCAN 2T PLUS. The

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DIGISCAN 2H PLUS and 2C PLUS systems essentially differ only in throughput time, cassette use/reuse time and cassette formats. Unlike the 2H PLUS and 2C PLUS, the DIGISCAN 2T PLUS is a thoracic imaging system that operates on the basis of phosphor plate technology and is configured with a generator, an overhead tube support with synchronization control, and an integrated X-ray tube.

Intended Use:

The DIGISCAN 2 PLUS recording system may be used for all radiographic exposures for which conventional cassettes are used, such as pediatrics, trauma, bone, neuro, GI, mobile radiography and vascular radiography.

Technological Characteristics:

The DIGISCAN 2 PLUS basic systems are comprised of an ID station, an X-ray reader and a diagnostic workstation. The ID station is an interactive station through which the trained healthcare professional may enter patient data and other exposure data. Included in the ID station configuration is a barcode reader and label printer for easy cassette identification. The X-ray reader reads out the radiographic information retained within the storage phosphor plates. The signal is then digitized and sent to an interactive diagnostic workstation (MagicView) where further postprocessing may be performed by a radiologist.

General Safety and Effectiveness Concerns:

Instruction for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and efficacious manner. The DIGISCAN 2 PLUS is a recording medium which does not come in direct contact with the patient, nor does it control the delivery of energy, the administration of parenteral drugs, or life sustaining functions. In addition, the wide dynamic range of the system minimizes the occurrence of over and under exposures, which concomitantly reduces the applied patient dosage.

Substantial Equivalence:

The SIEMENS DIGISCAN 2 PLUS is substantially equivalent to the SIEMENS DIGISCAN 2 which was described in K924459, and received FDA clearance on 12/17/92. The DIGISCAN 2 PLUS has been designed with increased throughput capacity and data management abilities compared to the predicate device DIGISCAN 2.

The X-ray readers configured with the DIGISCAN 2 PLUS systems are the Fuji AC-3, Fuji 9000 and the Fuji 9501 manufactured by FUJI Photo Company, Ltd.. The X-ray readers are new high throughput readers which were the subject of premarket notification K944046/S1 and received FDA clearance on May 11, 1995.

Kathleen Rutherford

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11/27/95
Date

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